UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,364	11/26/2003	Brian B. Lee	P-4962.00	9986

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EXAMINER
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ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

	Application No.	Applicant(s)
	10/723,364	LEE ET AL.
Office Action Summary	Examiner	Art Unit	
	Kai Rajan	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>26 November 2003</u>.

2a)☐ This action is **FINAL.**   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1 - 30</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1 - 30</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>February 11, 2005</u>.

4)☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

In the "Detailed Description of the Preferred Embodiments" portion of the specification,

the following items which appear in figures 1, 2, 3, 4, and 6 are not represented:

> Item 52 of figure 1
>
> Item 116 of figure 2
>
> Item 430 of figure 3
>
> Items 212 and 222 of figure 4
>
> Items 314 and 316 of figure 6

Appropriate correction is required.

Claim Objections

Claim 13 is objected to because of the following informalities:

Claim 13 recites features in the form of the alternative. The present disclosure is in the

improper form for a Markush group. Examiner suggests Applicant amends claim to read:

Claim 13. A method according to claim 1, further comprising:

storing the parameter values based upon one of the group consisting of: a discrete

classification, temporal resolution, and the total duration of storage time.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 9, 12, 14, 15, 20, 21, 26, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claims 2, 3, 9, 12, 14, 15, 20, 21, 26, and 27, the term "temporal resolution" is disclosed. This term renders the claims indefinite, since the depending claims and specification do not provide sufficient clarification of the definition of "temporal resolution." The Examiner has interpreted the applied prior art in a manner sufficient to reject the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 8, 10, 11, 13, 16, 17, 18, 19, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Duffin U.S. Patent No. 6,230,059.

Claim 1. A method for storing and processing physiological data in a medical recording

device having continuous data collection and data storage of such data in multiple time-resolved

tiers, comprising:

sampling one or more physiological signals at a selected sampling rate (Column 6 lines

44 – 59, figure 4 item S100);

deriving physiological parameter values from the sampled signal (Column 6 lines 44 –

59);

storing the parameter values as they are determined in a temporary memory buffer for a

predetermined storage interval (Figure 4 item S102);

determining a statistical aspect of the stored parameter values upon expiration of the

storage interval (Figure 5 item S202); and

writing the statistical aspect to a long-term memory buffer (Figure 4 items S115, S118).

Claim 7. A method according to claim 1, further comprising performing said method

based upon at least one of: a manually triggered event, a periodic event, an aperiodic event, a

time of day, an automatically triggered event (Column 8 lines 34 – 65).

Claim 8. A method according to claim 7, wherein said manually triggered event

comprises a manually-triggered telemetric method-initiation signal (Column 8 lines 34 – 65).

Claim 10. A method according to claim 1, wherein in the event that during performance

of the step of writing the statistical aspect to a long-term memory buffer said memory buffer

capacity is exceeded, then over-writing a portion of the previously-recorded statistical aspect

(Column 12 lines 25 – 37).

Claim 11. A method according to claim 10, wherein the portion comprises the least

recent portion of previously-recorded statistical aspect (Column 12 lines 25 – 37).

Claim 13. A method according to claim 1, further comprising:

storing the parameter values based upon a discrete classification of the stored parameters,

the temporal resolution of the stored parameters, or the total duration of storage time for said

stored parameters (Figure 4 items S114, S115, S118).

Claim 16. A method according to claim 1, wherein the temporary memory buffers

comprise histogram memory units and wherein the histogram memory units are assigned a value

or range of values of the stored parameters to store (Column 12 lines 14 – 24, figure 5 items

S212 and S214).

Claim 17. A method according to claim 16, wherein the histogram memory units are

assigned at least one of: a discrete percentile range, a median storage value, an upper percentile

value, a lower percentile value, as stored contents of said memory units (Column 12 lines 14 –

24, figure 5 items S212, S214).

Claim 18. A method according to claim 17, further comprising:

transferring the stored contents of some of the histogram memory units to the long-term

memory buffers (Figure 4 items S115, S118).

Claim 19. An apparatus for storing and processing physiological data in a medical

recording device having continuous data collection and data storage of such data in multiple

time-resolved tiers, comprising:

means for sampling one or more physiological signals at a selected sampling rate

(Column 6 lines 44 – 59, figure 4 item S100);

means for deriving physiological parameter values from the sampled signal (Column 6

lines 44 – 59);

means for storing the parameter values as they are determined in a temporary memory

buffer for a predetermined storage interval (Figure 3 item 40, figure 4 item S102);

means for determining a statistical aspect of the stored parameter values upon expiration

of the storage interval (Figure 5 item S202); and

means for writing the statistical aspect to a long-term memory buffer (Figure 4 items

S115, S118).

Claim 25. A computer readable medium for storing instructions for storing and

processing physiological data in a medical recording device having continuous data collection

and data storage of such data in multiple time-resolved tiers, comprising:

instructions for sampling one or more physiological signals at a selected sampling rate

(Column 6 lines 44 – 59, figure 4 item S100);

instructions for deriving physiological parameter values from the sampled signal

(Column 6 lines 44 – 59);

instructions for storing the parameter values as they are determined in a temporary

memory buffer for a predetermined storage interval (Figure 3 item 40, figure 4 item S102);

instructions for determining a statistical aspect of the stored parameter values upon

expiration of the storage interval (Figure 5 item S202); and

instructions for writing the statistical aspect to a long-term memory buffer (Figure 4

items S115, S118).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

Claims 2, 3, 4, 9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Duffin U.S. Patent No. 6,230,059 in view of Wateridge et al. U.S. Patent No. 5,355,891.

Claim 2. A method according to claim 1, wherein the long-term memory buffer

comprises at least two long-term memory buffers, and further comprising:

designating a unique temporal resolution to one of the at least two long-term memory

buffers.

In regards to claim 2, Duffin discloses a system for sampling, processing, and storing ECG signals in long-term memory (Duffin column 6 lines 44 – 59, figure 3 item 40, figure 4 items S100, S102, S115, S118, figure 5 item S102). Duffin fails to disclose designating unique temporal resolutions to the long-term memories. However, Wateridge et al. a reference in an analogous art teaches ECG data monitoring, processing, and storing in temporal resolution memory buffers and long term memory (Wateridge et al. column 4 lines 8 – 46, fig 1 items 13, 14). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the storage system of Duffin with the temporal resolution memory buffers of Wateridge et al., since Wateridge et al. teaches the ability to store data over an extended period of time without large memory and power requirements, resulting in a more portable apparatus (Wateridge et al. column 25 – 68).

Claim 3. A method according to claim 2, wherein the temporal resolution of one long-term memory buffer is determined by the predetermined storage interval (Wateridge et al. column 4 line 8 – column 5 line 2).

Claim 4. A method according to claim 2, wherein the at least two long-term memory buffers comprise digital memory buffers (Wateridge et al. column 4 lines 8 – 46).

Claim 9. A method according to claim 2, wherein the unique temporal resolution comprises at least a one of: a coarse resolution, a medium resolution, and a fine resolution (Wateridge et al. column 4 lines 8 – 46).

Claim 12. A method according to claim 2, wherein upon expiration of a predetermined

storage interval or upon exceeding available memory storage of a given long-term storage buffer

the following step is performed:

transferring a set of data comprising the statistical aspect or the stored parameter values

from a relatively higher temporal resolution storage medium to a relatively lower temporal

resolution storage medium (Wateridge et al. column 4 lines 8 – 46).

Claims 20, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Duffin U.S. Patent No. 6,230,059 in view of Wateridge et al. U.S. Patent No. 5,355,891.

In regards to claim 20, Duffin discloses a system for sampling, processing, and storing

ECG signals in long-term memory (Duffin column 6 lines 44 – 59, figure 3 item 40, figure 4

items S100, S102, S115, S118, figure 5 item S102). Duffin fails to disclose designating unique

temporal resolutions to the long-term memories. However, Wateridge et al. a reference in an

analogous art teaches ECG data monitoring, processing, and storing in temporal resolution

memory buffers and long term memory (Wateridge et al. column 4 lines 8 – 46, fig 1 items 13,

14). It would have been obvious to one of ordinary skill in the art at the time of the invention to

modify the storage system of Duffin with the temporal resolution memory buffers of Wateridge

et al., since Wateridge et al. teaches the ability to store data over an extended period of time

without large memory and power requirements, resulting in a more portable apparatus

(Wateridge et al. column 25 – 68).

Claim 21. An apparatus according to claim 20, wherein the temporal resolution of one

long-term memory buffer is determined by the predetermined storage interval (Wateridge et al.

column 4 line 8 – column 5 line 2).

Claim 22. An apparatus according to claim 20, wherein the at least two long-term

memory buffers comprise digital memory buffers (Wateridge et al. column 4 lines 8 – 46).

Claims 26, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Duffin U.S. Patent No. 6,230,059 in view of Wateridge et al. U.S. Patent No. 5,355,891.

In regards to claim 26, Duffin discloses a system for sampling, processing, and storing

ECG signals in long-term memory (Duffin column 6 lines 44 – 59, figure 3 item 40, figure 4

items S100, S102, S115, S118, figure 5 item S102). Duffin fails to disclose designating unique

temporal resolutions to the long-term memories. However, Wateridge et al. a reference in an

analogous art teaches ECG data monitoring, processing, and storing in temporal resolution

memory buffers and long-term memory (Wateridge et al. column 4 lines 8 – 46, fig 1 items 13,

14). It would have been obvious to one of ordinary skill in the art at the time of the invention to

modify the storage system of Duffin with the temporal resolution memory buffers of Wateridge

et al., since Wateridge et al. teaches the ability to store data over an extended period of time

without large memory and power requirements, resulting in a more portable apparatus

(Wateridge et al. column 25 – 68).

Claim 27. A medium according to claim 26, wherein the temporal resolution of one long-term memory buffer is determined by the predetermined storage interval (Wateridge et al. column 4 line 8 – column 5 line 2).

Claim 28. A medium according to claim 26, wherein the at least two long-term memory buffers comprise digital memory buffers (Wateridge et al. column 4 lines 8 – 46).

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffin U.S. Patent No. 6,230,059 as applied to claim 1 above, in view of Nikolic et al. U.S. Patent No. 5,743,267, and further in view of Brown U.S. Patent No. 5,997,476.

In regards to claim 5, Duffin discloses a system for sampling, processing, and storing ECG signals (Duffin column 6 lines 44 – 59, figure 3 item 40, figure 4 items S100, S102, S115, S118, figure 5 item S102). Duffin fails to disclose the sampling, processing, and storing of other physiological signals such as blood pressure. However, Nikolic et al. a reference in an analogous art teaches sampling, processing, and storing blood pressure data (Nikolic et al. column 3 line 30 – column 4 line 32, column 10 lines 55 – 65). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the ECG sensor system of Duffin with the blood pressure monitoring system of Nikolic et al., since Brown a reference in an analogous art states that one sensor may be interchanged with another based on the condition being monitored (Brown column 4 line 64 – column 5 line 13).

Claim 6. A method according to claim 5, further comprising calculating a mathematical derivative, a mathematical integral or a percentile value of the one or more physiologic signals or the stored parameters (Nikolic et al. column 8 line 40 – column 9 line 18, column 10 lines 42 – 65).

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffin U.S. Patent No. 6,230,059 as applied to claim 19 above, in view of Nikolic et al. U.S. Patent No. 5,743,267, and further in view of Brown U.S. Patent No. 5,997,476.

In regards to claim 23, Duffin discloses a system for sampling, processing, and storing ECG signals (Duffin column 6 lines 44 – 59, figure 3 item 40, figure 4 items S100, S102, S115, S118, figure 5 item S102). Duffin fails to disclose the sampling, processing, and storing of other physiological signals such as blood pressure. However, Nikolic et al. a reference in an analogous art teaches sampling, processing, and storing blood pressure data (Nikolic et al. column 3 line 30 – column 4 line 32, column 10 lines 55 – 65). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the ECG sensor system of Duffin with the blood pressure monitoring system of Nikolic et al., since Brown a reference in an analogous art states that one sensor may be interchanged with another based on the condition being monitored (Brown column 4 line 64 – column 5 line 13).

Claim 24. An apparatus according to claim 23, further comprising:

means for calculating a mathematical derivative, a mathematical integral or a percentile

value of the one or more physiologic signals or the stored parameters (Nikolic et al. column 8

line 40 – column 9 line 18, column 10 lines 42 – 65).

Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Duffin U.S. Patent No. 6,230,059 as applied to claim 25 above, in view of Nikolic et al. U.S.

Patent No. 5,743,267, and further in view of Brown U.S. Patent No. 5,997,476.

In regards to claim 29, Duffin discloses a system for sampling, processing, and storing

ECG signals (Duffin column 6 lines 44 – 59, figure 3 item 40, figure 4 items S100, S102, S115,

S118, figure 5 item S102). Duffin fails to disclose the sampling, processing, and storing of other

physiological signals such as blood pressure. However, Nikolic et al. a reference in an analogous

art teaches sampling, processing, and storing blood pressure data (Nikolic et al. column 3 line 30

– column 4 line 32, column 10 lines 55 – 65). It would have been obvious to one of ordinary skill

in the art at the time of the invention to modify the ECG sensor system of Duffin with the blood

pressure monitoring system of Nikolic et al., since Brown a reference in an analogous art states

that one sensor may be interchanged with another based on the condition being monitored

(Brown column 4 line 64 – column 5 line 13).

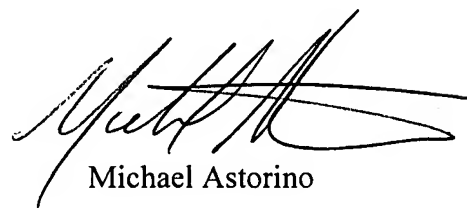Claim 30. A medium according to claim 29, further comprising:

instructions for calculating a mathematical derivative, a mathematical integral or a

percentile value of the one or more physiologic signals or the stored parameters (Nikolic et al.

column 8 line 40 – column 9 line 18, column 10 lines 42 – 65).

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Kai Rajan whose telephone number is 571-272-3077. The

examiner can normally be reached on Monday-Friday 9:00AM to 5:00PM.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

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KR
April 30, 2007

Michael Astorino